The ATHENA Breast Health Network
Executive Summary
July 23, 2009

Overview: Advances in science and information technology have far outpaced the progress made in systems for delivery of health services. The ATHENA Breast Health Network is a large-scale demonstration project that will drive innovation in breast cancer screening, treatment, and prevention, ultimately serving as a model for effectively and efficiently changing the paradigm for health care delivery.

The Problem: Breast cancer is a common, devastating and costly disease that poses a significant threat to women. The United States spends more than $20 billion annually on screening and treatment of breast cancer. There are significant opportunities to reduce those costs while improving the quality of care. The data being used to understand the risk of breast cancer is vastly outdated – having been collected in the 1970s and 80s. Two decades after the implementation of nationwide screening mammography in the United States, we have observed that there is a significant increase in the detection of low risk cancers. However, there has been a significant increase in overall cancers as well as localized cancers, largely in the age group 50 and older, without a concomitant decrease in the rate of regional cancers. This phenomenon has also been described in countries with nationwide screening programs. Screening has resulted in some reduction in death from the disease, but it has not eliminated aggressive, high risk cancers. A study recently released by the Cochrane Center in Copenhagen contends that the one in three breast cancer patients in public screening programs may reflect over-diagnosis of indolent disease which may then be unnecessarily treated. This is in contrast to aggressive stage 2 and stage 3 cancers which may not be identified through early detection. In the I-SPY TRIAL, a multicenter cooperative group neoadjuvant breast cancer trial for women with stage 2 and 3 disease, 85% of women being screened had interval cancers presenting between normal screens. Clearly, screening and early detection will have to be better tailored if we want to reduce the risk of death from breast cancer.

More than 44,000 women still die from breast cancer each year and over 200,000 women are diagnosed each year. While we do not have optimal treatments for some, thousands of women are getting expensive, toxic treatments that may do more harm than good. And for those with highest risk disease, we often do not have the optimal treatments. We need to be smarter about how we use the billions of dollars that are spent each year to prevent, screen for and treat breast cancer.

The Opportunity: The science fueling personalized medicine is experiencing explosive growth. Molecular tests are now available that can analyze a breast cancer tumor and categorize the risk of breast cancer recurrence with and without treatments. Giving doctors sophisticated tools to tailor treatments to the individual tumor will revolutionize care – potentially enabling thousands of women to safely forgo toxic treatments and providing those at high risk of dying from their cancer with more targeted and effective treatments. Equally, if not more exciting, is the promise of molecular tools to more accurately predict the risk of getting breast cancer, which may ultimately lead to better ways to prevent the disease. A number of these tools are ready for use today, and many more can be developed and validated. A big challenge will be to determine how to best change and improve routine care.

Our Solution: The ATHENA Breast Health Network, a large-scale demonstration project, will integrate clinical care and research to drive innovation in prevention, screening, treatment and management of breast cancer and, at the same time, revolutionize the delivery of care.

An innovative collaboration across the 5 University of California medical centers, the UCSF Institute for Health Policy Studies, the School of Public Health at Berkeley, the California Institute for Quantitative Biosciences, and Lawrence Berkeley National Laboratories, ATHENA will drive innovation in breast cancer prevention, screening, treatment and survivorship by creating a 21st century "knowledge economy" to continuously learn from all women receiving care, rather than just the small fraction of women participating in clinical trials.

By working together as a community, the University of California medical centers, their affiliates, primary care and specialty physicians will work to change the options for patients today and create a better future for all women at risk to develop breast cancer. By standardizing the collection of structured data from both patients and physicians that will be computable and interoperable, integrating molecular profiling at the time of diagnosis, and creating an unparalleled biospecimen repository, the ATHENA Breast Health Network will enable personalized care informed by science, and fuel continuous improvement in treatment options and outcomes. ATHENA will require a re-engineering of current processes, integration of clinical and research processes starting at the point of care, as well as communication among specialty and primary care. The anchoring ATHENA projects will be to:

- Automate the identification of women at high risk for breast cancer through the screening process, and offer a web-based prevention consultation and decision support;

- Implement models for coordinating diagnostic evaluation, likely to safely eliminate 25% of biopsies;
- Conduct molecular profiling at the time of diagnosis and offer fewer interventions for very low risk cancers, and build models to predict high risk cancers;
- Identify women with the highest risk cancer diagnoses, offer them risk-based treatment interventions, and refer them to cutting edge adaptive design trials;
- Identify women with co-morbidities associated with higher mortality and offer targeted lifestyle interventions;
- Provide molecular profiles for women with metastatic cancer and build targeted novel therapies.

The ATHENA Breast Health Network is partnering with innovative national efforts, including BIG Health and the Center for Medical Technology Policy (CMTP). BIG Health is a broad-based initiative from the National Institutes of Health (NIH) led by Ken Buetow to develop common tools and platforms for research and care. The Center for Medical Technology Policy (CMTP), led by Sean Tunis, is leading an effort to engage payers, policymakers, and other key stakeholders to develop and implement comparative effectiveness analyses and to experiment with novel financing of biomarker development, data sharing, and ways to reduce transaction costs. If successful, the ATHENA network will become a model system for speeding validation, delivery and approval of new diagnostics and effective tailored therapies.

Critical to the success of ATHENA is the design and implementation of common methods, tools, and infrastructure, including:

- A comprehensive informatics strategy that includes innovative tools to collect, analyze and distribute data in real time from and among all stakeholders to create public databases and improve health;
- Comparative effectiveness research infrastructure supported by shared web-based decision tools for patients and providers to translate clinical evidence into actionable treatment options at the point-of-care, allowing physicians to tailor treatment to biology and patient preference, and clinical performance;
- Realignment of incentives to encourage the most appropriate prevention and treatment options and payment strategies that reward quality, evidence-based care, data collection, knowledge generation, and appropriate care rather than unproven interventions;
- A data and biospecimen repository to enable large-scale, comparative effectiveness research and long-term, longitudinal studies (similar to the Framingham study) to enable tailored prevention and treatment strategies.

The goal of the ATHENA Breast Health Network is to improve survival and reduce suffering from breast cancer by creating a twenty first century knowledge economy, which will accelerate research, shorten knowledge turns, and compress the time to implement innovations in clinical

practice. The infrastructure for the project will be reusable and scalable nationally, not only for breast cancer, but many other medical conditions.

Summary and Implications: The overarching goal of ATHENA is to provide dramatically improved efficiency, effectiveness and functionality for clinicians, patients, and researchers. The data and results will lead to evidence-based innovations in the diagnosis and treatment of cancer, as well as changes to the way patients and providers interact to prevent and manage the disease. Today, every researcher and every company has to develop their own data repository. As a result, the studies are small, time consuming, expensive, and the results are not representative of the general population. The ATHENA Breast Health Network's biospecimen and data repository will be an incredible resource, and will fuel innovation and jobs in life sciences, enabling the United States to maintain its position at the cutting edge of genomic research. Further, it can also lead to new payment methods which create incentives for the most cost-effective treatment.

Although the ATHENA Breast Health Network focuses on breast cancer, the tools and infrastructure developed for this project are readily transferable to other cancers and conditions. ATHENA will serve as a model to drive innovation and change health care delivery. We anticipate that this ambitious project will create new systems and significantly change the culture of research and clinical practice to become the new standard of care within 5 years. The learning system created will continue to evolve until we have cured this disease.

Funding: Initial funding ($10 million) has already been raised, and plans are in place to make the network sustainable through grants and foundation commitments. We plan to raise an additional $20 million dollars for infrastructure to build scalable tools for computable information collection and exchange among patients and providers, including between primary care and specialty physicians and to build tools for repositories that can generate new knowledge and inform clinical care.

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